DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	12/08/2010 - 01/06/2011* FEI NUMBER 1000221357

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mark M. Sieczkarek, President and CEO

FIRM NAME	STREET ADDRESS
Conceptus, Inc.	331 E.Evelyn Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mountain View, CA 94041	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically, the following complaints from July 12, 2010 to Dec. 10, 2010 both report a bowel perforation that occurred during the procedure to place the firm's product:

1. (b) (4) incident and aware date of 11/3/2010: Perforation from scope; patient taken to hospital for exploratory laparoscopy. Resolution notes on 12/21/2010 states patient had bowel perforation with some hemorrhage. Patient had a hysterectomy.

2. (b) (4) incident and aware date of 11/16/2010: When doctor attempted to place second device, she used graspers to locate the ostium. She perforated the patients bowel.

In both complaints the firm's device did not directly cause the injury, but the procedure for use required the use of an hysteroscope and visualization of the tubal ostium. There were 41 complaints of perforation from July 12, 2010 to Dec. 10, 2010 the above two complaints were the only two of the 41 that involved perforation of the bowel. The other complaints were for uterus or fallopian tubes.

There was one complaint that was not for a perforation but for which a CT scan showed that the insert was in two pieces with one of the pieces outside of the tube between the uterus and the bowel:

3. (b) (4) incident date 11/05/2010, aware date 12/16/2010: Patient reported pain immediately following the procedure. Essure procedure done on 11/5/10 Performed a CT scan which revealed device was in 2 pieces; proximal part was in isthemal portion; distal between uterus and bowel.Physician plans laparoscopic removal tomorrow and tubal ligation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Timothy C. Grome, Investigator	DATE ISSUED 01/06/2011

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OBSERVATION 2

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, the firm received complaints that a perforation had occurred with the coil micro-insert being seen radiographically outside of the Fallopian Tube in the abdominal cavity:

1. (b) (4) incident and aware date 10/01/2010: perforation 2 HSGs showed device was located in the peritoneum. The micro-insert was removed during a laparoscopic tubal ligation.

2. (b) (4) incident date 10/05/2010, aware date 10/08/2010: Perforation; 1 micro-insert is in the peritoneal cavity. Essure was placed in June 2010 patient is asymptomatic.

3. (b) (4) incident date 5/11/2010, aware date 10/21/2010: Perforation observed on HSG. Essure procedure done 5/11/10. HSG shows device is outside the tube on the left side in the peritoneal cavity.

4. (b) (4) incident date 10/26/2010, aware date 10/26/2010: Perforation; on HSG micro-insert observed in the peritoneal cavity.

5. (b) (4) incident date 09/01/2010, aware date 12/10/2010: Perforation: micro-insert located outside the tube in the cul-de-sac. Essure done on 09/01/10; no HSG done 12/09/10. Patient is asymptomatic.

During the time period of July 12, 2010 to January 4, 2011 there were 45 complaints for perforation. Two for perforation of bowel, of all the other for perforation of the tube two ((b) (4)) were reported as MDRs in one (b) (4) the patient complained of bleeding, in the other (b) (4) the patient underwent surgery to remove the micro-insert. The five complaints listed above were the other complaints involving a perforation of the uterus or fallopian tube in which the micro-insert was located in the peritoneal cavity.

OBSERVATION 3

Risk analysis is incomplete.

Specifically, Design Failure Modes Effects Analysis (DFMEA) for Essure ESS305 Document Number (b) (4) does not include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity. Since December 2007 according to complaint database provided by the firm there have been 508 complaints with the subject including perforation. 168 of these complaints were of the subject perforation (micro-insert), and 5 were expulsion/perforation. In the same time period according to the list of Medical Device Reports, there were 3 complaints reported for pain/perforation, 18 complaints for perforation and one for perforation and bleeding. In the database supplied with a complaint description I found 4 complaints of perforation from July 20, 2010 to Dec. 10, 2010 in which the micro-insert coil was found on x-ray to be in

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the peritoneal cavity.

OBSERVATION 4

Corrective and preventive action activities and/or results have not been documented.

Specifically, after failures in Design of Experiment for requalification of manufacture of microinsert coil catheters produced failing results on 11/30/2010, (b) (4), your firm's engineers learned from telephone conversations with engineers from your contract manufacturer (b) (4) that delivery wires used for the test lots were taken from quarantine without having the components fully certified. (b) (4). Your firm did not receive the contract manufacturer's CAPA report until 12/21/2010. That CAPA did not mention the non-conformity of your contract manufacturer not following their own SOP for control of non-conforming material. Your firm covered this deviation under CAPA (b) 10/25/10 opened to document actions taken to address the detachment failures noted during lot release of (b) (4) ESS305 as documented in (b) (4).

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OBSERVATION 4

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ANNOTATIONS
OBSERVATION 1
(b) (4)

(b) (4)

OBSERVATION 2
(b) (4)

OBSERVATION 3
(b) (4)

OBSERVATION 4
Corrected and Verified
1/6/2011

AMENDMENT 1

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